

82
84WHAT IS CLAIMED IS:

1. An isolated nucleic acid molecule encoding prostate cancer antigen 3 (PCA3).

5

2. The isolated nucleic acid molecule according to claim 1 comprising a polynucleotide sequence at least 90% identical to a sequence selected from the group consisting of:

(a) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:2;

(b) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:7;

(c) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97;

(d) a nucleotide sequence encoding a PCA3 polypeptide comprising the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521; and

(e) a nucleotide sequence complementary to any of the nucleotide sequences in (a), (b), (c), or (d).

25

83
85

3. The isolated nucleic acid molecule according to claim 1, wherein the molecule comprises the nucleotide sequence encoding PCA3 as set forth in SEQ ID NO:1 or 6.

5 4. The isolated nucleic acid molecule according to claim 1 comprising the nucleotide sequence set forth in SEQ ID NO:1, 3, 4, or 6.

10 5. The isolated nucleic acid molecule according to claim 1, wherein the molecule encodes the polypeptide comprising the complete amino acid sequence set forth in SEQ ID NO:2 or 7.

15 6. The isolated nucleic acid molecule according to claim 1, wherein the nucleotide sequence encoding a PCA3 polypeptide comprises the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97, respectively.

20 7. The isolated nucleic acid molecule according to claim 1, wherein the nucleotide sequence encoding a PCA3 polypeptide comprises the complete amino acid sequence encoded by the polynucleotide clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521, respectively.

25 8. An isolated nucleic acid molecule consisting of 10 to 50 nucleotides which specifically hybridizes to RNA or DNA encoding

84
85

PCA3, wherein said nucleic acid molecule is or is complementary to a nucleotide sequence consisting of at least 10 consecutive nucleotides from PCA3 exon 1, 2, 3, 4a, 4b, 4c, or 4d, wherein said nucleic acid molecule does not specifically hybridize to nucleotides 511-985 of SEQ ID NO:1, to nucleotides 567-961 of SEQ ID NO:1, to nucleotides 533-1007 of SEQ ID NO:6 or to nucleotides 589-983 of SEQ ID NO:6.

9. A method of detecting PCA3 nucleic acid in a sample comprising:

a) contacting said sample with the nucleic acid molecule according to claim 8, under conditions such that hybridization occurs, and

b) detecting the presence of said molecule bound to PCA3 nucleic acid.

10. A kit for detecting the presence of PCA3 nucleic acid in a sample comprising at least one container means having disposed therein the nucleic acid molecule according to claim 8.

11. A recombinant nucleic acid molecule comprising, 5' to 3', a promoter effective to initiate transcription in a host cell and the nucleic acid molecule according to claim 1.

12. A recombinant nucleic acid molecule comprising a vector and the nucleic acid molecule according to claim 1.

85
87

13. A cell that contains the recombinant nucleic acid molecule according to claim 11.

14. A non-human organism that contains the recombinant nucleic acid molecule according to claim 11.

15. A purified PCA3 polypeptide or an epitope-bearing portion thereof.

16. The purified PCA3 polypeptide according to claim 14 comprising an amino acid sequence at least 90% identical to a sequence selected from the group consisting of:

(a) the amino acid sequence of the PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:2;

(b) the amino acid sequence of the PCA3 polypeptide comprising the complete amino acid sequence in SEQ ID NO:7;

(c) the amino acid sequence of the PCA3 polypeptide comprising the complete amino acid sequence encoded by the cDNA clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 682.97;

(d) the amino acid sequence of the PCA3 polypeptide comprising the complete amino acid sequence encoded by the cDNA clone contained in the deposit at the Centraal voor Schimmelcultures as accession number CBS 100521; and

(e) the amino acid sequence of an epitope-bearing portion of any one of the polypeptides of (a), (b), (c), or (d).

86
88

17. An antibody having specific binding affinity to the polypeptide or epitope-bearing portion thereof according to claim 15.

5 18. A method of detecting PCA3 in a sample, comprising:

- a) contacting said sample with an antibody according to claim 17, under conditions such that immunocomplexes form, and
- b) detecting the presence of said antibody bound to said polypeptide.

10

19. A diagnostic kit comprising:

- a) a first container means containing the antibody according to claim 17 and
- b) second container means containing a conjugate comprising a binding partner of said monoclonal antibody and a label.

15

20. A hybridoma which produces the monoclonal antibody according to claim 17.

20

21. A method of treatment of prostate cancer in a mammal, comprising administering a therapeutically effective amount of the antibody of claim 17 to said mammal.

25

22. A method of treatment of prostate cancer in a mammal, comprising administering a therapeutically effective amount of an antisense PCA3 nucleic acid molecule.

87
89

23. A method of diagnosing the presence or predisposition to develop prostate cancer in a patient, said method comprising:

- 5 a) taking a sample from said patient;
- b) determine the amount of PCA3 RNA or PCA3 protein in said sample, and
- c) diagnosing the presence or predisposition to develop prostate cancer in a patient wherein an increased amount of PCA3 RNA or protein as compared to a patient without prostate cancer
- 10 indicates the presence or predisposition to develop prostate cancer.

Add
C3Q
Add
J2

add
E4